

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-21, 23-25 and 27-28 are pending. Claim 1 is amended by incorporating the limitations of claims 7-8. Claim 15 is amended to be drawn to the elected invention by combining the limitations of original claims 1-2, 4 and 6-7 as well as the specification (e.g., page 4, lines 2-6). Claims 8 and 28 are based on page 5, lines 23-24, of the specification (i.e., “RNA expression levels and/or protein expression levels . . . may be temporarily or structurally altered”). Claims 7 and 27 are based on page 3, lines 23-24, of the specification (i.e., “not dependent on antibiotic or other selection markers”).

Applicant repeats his request for rejoinder because non-elected claims 10-14, 16-21 and 23-25 are related to the elected invention as subcombination-combination. Applicant cancels non-elected claim 26 without prejudice to future prosecution of that subject matter.

The Examiner required compliance with the sequence rules. But in a telephone conversation on March 12, 2009, she clarified that her reference to the specification should have been to paragraph [0038]. Applicant amended the specification by inserting sequence identifiers and submitted the Sequence Listing (both paper and computer readable copies) on January 18, 2007. Therefore, it is submitted that this application complies with the sequence rules and withdrawal of the requirement is requested.

A typographical mistake in claim 3 is corrected in the present set of claims. Thus, withdrawal of the objection to the claim is requested.

### 35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-4 and 6-9 were rejected under Section 102(b) as allegedly anticipated by Wolff et al. (U.S. Patent 6,262,252). Applicant traverses.

As an initial matter, it is noted that the paragraph numbers cited by the Examiner in the Office Action are not listed on the '252 patent as printed. It appears, however, that the relevant portion of the disclosure is Example 11. For clarity of the record, Applicant respectfully requests that future citations in the Office Action to the '252 patent refer to its column and line numbers.

The present claims 1 and 15 are not anticipated by Wolff. To the extent that gene transfer requires (i) transfection of DNA into a host cell and (ii) a change in metabolism of the modified host cell by the transfected DNA, Applicant does not agree with the allegation that Wolff discloses gene transfer (it is unclear what portion of the disclosure is cited by reference to paragraph 57). Neither was the isolation of transfected host cells disclosed by Wolff since, at most, transfected host cells were detected by fluorescent microscopy. But there was no isolation or separation of the transfected host cells from non-transfected cells. There was also no evidence presented in the '292 patent of a permanent change in metabolism in transfected cells. The DNA used by Wolff (i.e., pCIIuc) was later described in more detail by Danko et al. (Hum. Mol. Genetics, 6:1435-1443, see attached). Danko makes clear that transfection of host cells using the pCIIuc DNA had only temporary effects on gene expression.

Claims 1-9 were rejected under Section 102(b) as allegedly anticipated by Johnson et al. (AAPS Pharmsci 1:article 6, 1999). Applicant traverses.

The present claims 1 and 15 are not anticipated by Johnson. To the extent that gene transfer requires (i) transfection of DNA into a host cell and (ii) a change in metabolism of the modified host cell by the transfected DNA, Applicant does not agree with the allegation that Johnson discloses gene transfer because the perinuclear staining (i.e., around the nucleus instead of being expressed) is not indicative of the entry of DNA into the host cell's nucleus where it would be required for any change in metabolism. There was also no isolation or separation of the transfected host cells from non-transfected cells.

Withdrawal of the Section 102 rejections is requested because the cited documents fail to disclose all limitations of the claimed invention.

*Conclusion*

Having fully responded to the pending Office Action, Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if additional information is required.

Respectfully submitted,

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